Supreme Court, U.S.
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IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1994

STANISLAW R. BURZYNSKI, M.D., Ph.D.

Petitioner

vs.

TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST

Respondent

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

# APPENDIX TO PETITION FOR WRIT OF CERTIORARI

## VOLUME II

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# EXHIBIT "F"

DOCKET NO. 503-92-529

| | | |
|---|---|---|
| IN THE MATTER OF THE COMPLAINT AGAINST | )( | BEFORE THE TEXAS |
| | )( | STATE BOARD OF |
| STANISLAW R. BURZYNSKI, M.D., PH.D., RESPONDENT | )( | MEDICAL EXAMINERS |

## ORDER

On the 20th day of August, 1994, came on to be heard for final action by the Texas State Board of Medical Examiners, ("the Board") duly in session, the matter of The Texas medical license of STANISLAW R. BURZYNSKI, M.D., PH.D., RESPONDENT herein, wherein the Board was represented by Dewey E. Helmcamp, III, Assistant Attorney General, and the RESPONDENT appeared and was represented by Richard A. Jaffe, Attorney. It was alleged that RESPONDENT. violated Section 3.08 subsections (4)(A), (4)(G), and (6) of article 4495b, Texas Revised Civil Statutes. The matter was heard in public hearing on May 24, 1993, and May 25, 1993, before Earl A. Corbitt, Administrative Law Judge. After consideration of the Proposal for Decision submitted to the Board by the Administrative Law Judge, the Board makes the following findings of fact hereby denying any and all findings of fact proposed by any party not specifically made herein:

## FINDINGS OF FACT

1. The parties, the Texas State Board of Medical Examiners and Stanislaw R. Burzynski, M.D., Ph.D., stipulated that they received proper and timely notice of the hearing.

2. Stanislaw R. Burzynski, M.D., Ph.D., (RESPONDENT) is licensed to practice medicine in the State of Texas and is the holder of Texas Medical License No. D-9377.

3. The RESPONDENT operates a clinic in Houston, Texas, in which he treats cancer patients and AIDS patients with substances known as "antineoplastons".

4. Antineoplastons are peptides.

5. Antineoplastons are not approved for commercial interstate

marketing by the Food and Drug Administration (FDA). The Food and Drug Administration has not issued a letter of approval or letter of approvability regarding antineoplastons.

6. The RESPONDENT stipulated that from 1977 until August 14, 1992, the date of the Second Amended Complaint, he administered antineoplastons to his patients.

7. In an Order, filed May 24, 1983, and entered in Cause Number H-83-2069, United States of America v. Burzynski Cancer Research, Institute, et al, in the United States District Court for the Southern District of Texas, Houston Division, antineoplastons A2, A3, A5, A10, and AS2-1 were found to be

"drugs" within the meaning of Federal law and "new drugs" within the meaning of Federal law. Antineoplastons A2, A3, A5, A10, and AS2-1 are here found to be "drugs" and "new drugs" in agreement with the Court's Order. Antineoplastons are further found to be "drugs" and "new drugs" within the meaning of Texas statutes.

8. No evidence was admitted, either by document or by testimony, that antineoplastons A, AS2-5 or AS-5 are "drugs" or "new drugs" as defined in Federal law. By inference from testimony provided by Respondent regarding the nature and use of all types of these agents, antineoplastons A, AS2-5 and AS-5 are here found to be "drugs" and "new drugs" within the meaning of Texas statutes.

9. In 1977, the RESPONDENT sought legal advice regarding whether he could lawfully manufacture antineoplastons and use them in the treatment of his patients in the State of Texas.

10. In 1977, Hal Nelson, then General Counsel, Texas Department of Health, and Bob Henna, then Director of the Division of Food and Drugs, Texas Department of Health,, were asked to render opinions whether the RESPONDENT could lawfully manufacture antineoplastons and use them in the treatment of his patients in the State of Texas.

11. Although evidence was presented that Hal Nelson

and Bob Henna each orally expressed the opinion that the RESPONDENT would not be in violation of the Texas Food, Drug and Cosmetic Act by manufacturing antineoplastons and using them in the treatment of his patients no written order or grant of permission regarding these activities was extended to RESPONDENT by afiy employee or representative of the Texas Department of Health.

12. RESPONDENT testified that, in reliance upon the legal advice, described in Finding of Fact No. 9, and the oral opinion of the officials responsible for the administration of the Texas Food, Drug and Cosmetic Act, described in Findings of Fact Nos. 10 and 11, the RESPONDENT turned down an offer of a tenured position and substantial research funding from the University of Tennessee, and opened his clinic and laboratory facility in Houston, Texas.

13. On May 24, 1983, an Order was issued by the Federal Court, as referenced in Finding of Fact No. 7, which enjoined the RESPONDENT from shipping antineoplastons interstate unless the RESPONDENT first obtained approval of the Food and Drug Administration.

14. Since the Federal Court which heard the case referenced in Finding of Fact No. 7 was without authority to regulate intrastate commerce in antineoplastons, the Order described in Finding of Fact No. 13 contained a statement that

said Order did not apply to the RESPONDENT'S manufacture or use of antineoplastons within the State of Texas.

15. From 1980 forward, officials within the Texas Department of Health were aware of the RESPONDENT'S manufacture and use of antineoplastons. The Department maintained contact with the Food and Drug Administration and followed the FDA's attempt to obtain an injunction against the RESPONDENT. (See Finding of Fact No. 13).

16. At no time pertinent to the allegations against the RESPONDENT did the Texas Department of Health adopt rules related to the use in Texas of drugs which were not approved by the Food and Drug Administration.

17. RESPONDENT'S use of antineoplastons prior to. September I, 1985, was not solely for investigational use.

18. On May 2, 1988, the Texas Department of Health issued a letter to the RESPONDENT advising the RESPONDENT that his use of antineoplastons was considered to be in violation of Section 18 of the Texas Food, Drug and Cosmetic Act.

19. In 1992, the Texas Department of Health filed suit against the RESPONDENT seeking to enjoin his manufacture and use of antineoplastons and seeking to destroy his stock on hand.

20. Many of the cancer patients treated by the

RESPONDENT have been previously treated with radiation therapy and chemotherapy but have failed to respond. The condition of many of the RESPONDENT'S patients is believed to be terminal with no further conventional treatment available.

21. RESPONDENT, Nicholas Patronas, M.D., Chief of the Section of Neuroradiology, National Institutes of Health; Fred J. Epstein, M.D.; patient T.M.S., a medical doctor; the father of patient D.M., and the physicians treating patients S.C., P.M., M.J.S., testified that, in their opinion, antineoplaston therapy is necessary for the survival of many of the RESPONDENT'S patients.

22. No evidence was received at hearing that was contrary to the testimony described in Finding of Fact No. 21.

23. The efficacy of antineoplastons in the treatment of human cancers is not of issue in these proceedings.

24. Prior to June 1983 the RESPONDENT filed with the FDA a "Notice of Claimed Investigational Exemption for New Drug" (IND) for a study of the use of antineoplaston A-10 in the treatment of advanced breast cancer. On February 13, 1984, the RESPONDENT was notified by letter from the FDA that this proposed study had been placed on "clinical hold". in that he was not to proceed further with the study until he received further authority from the FDA. On March 16, 1989 the FDA, by letter granted such authority and released the clinical hold only with

respect to antineoplaston A-10. No, authority was granted nor was the clinical hold released in relation to any other antineoplaston utilized by RESPONDENT.

25. The RESPONDENT treated patients with antineoplaston A-10 between February 13, 1984, and March 16, 1989.

26. The RESPONDENT stipulated that he treated the 40 individuals as alleged in Count II, including treatment with one or more of the following antineoplastons other than A-10: At A-2t A-3, A-5, AS2-11 AS2-5, and AS-5.

27. After May 2, 1988, and through August 31, 1989, RESPONDENT's treatment of patients with antineoplastons constituted a deliberate and knowing violation of the provisions of the Texas Food,, Drug and Cosmetic Act pertaining to the sale, delivery, and use of "new drugs" in the state of Texas.

28. The codification of the Texas Food, Drug and Cosmetic Act in the Texas Health and Safety Code became effective on September 1,, 1989.

29. From September 1, 1989, through August 14, 1992, RESPONDENT'S treatment of patients with antineoplastons constituted a deliberate and knowing violation of the provisions of the Health and Safety Code of Texas pertaining to the sale, delivery, and use of "new drugs" in the state of Texas.

30. The RESPONDENT provided persons interested in

antineoplaston therapy with an informational brochure which contained representations that antineoplastons affect cancers.

31. The RESPONDENT provided persons interested in antineoplaston therapy, upon request, with articles which contained representations that antineoplastons affect cancers.

32. There was no evidence that the representations described in Findings of Fact Nos. 30 and 31 are, in facto false.

33. Representations to the effect that a drug will affect cancers, such as the representations described in materials provided to persons interested in antineoplastons, as described in Findings of Fact Nos. 30 and 31, are representations that said drug will affect neoplasms.

34. The RESPONDENT has two INDs approved. IND #22,029 provides for a study of the use of antineoplaston A-10 capsules in the treatment of advanced breast cancer. IND #40,576 provides for a study of the use of antineoplaston AS2-1 capsules in the treatment of persons infected with HIV.

35. The RESPONDENT had not initiated clinical trials under either IND #22,029 or IND #40,576.

36. No evidence was offered by which a reasonable charge for treatment of patients for cancer using antineoplastons could be determined.

37. No evidence was offered by which a reasonable charge for treatment of persons infected with HIV using

antineoplastons could be determined.

38. At all times pertinent to the allegations, the RESPONDENT has charged his patients a fee for antineoplaston therapy.

## CONCLUSIONS OF LAW

Based upon the above Findings of Fact, the Board concludes that:

1. The Texas State Board of Medical Examiners has jurisdiction over this matter under Tex. Rev. Civ. Stat. Ann. art. 4495b, the Texas Medical Practice Act.

2. The RESPONDENT received proper notice of the hearing pursuant to Tex. Rev. Civ. Stat. Ann. art. 6252-13a and the Texas Medical Practice Act.

3. Pursuant to the Texas Medical Practice Act, Section 4-Oll the Texas State Board of Medical Examiners has authority to take disciplinary action against any of its licensees for conduct specified in the Texas Medical Practice Act,, Section 3.08,, which includes:

(4) unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public. Unprofessional or dishonorable conduct likely to deceive or defraud the public includes but is not limited to the following acts:

(A) committing any act that is in violation of the laws

of the State of Texas if the act is connected with the physician's practice of medicine.....

(G) persistently and flagrantly overcharging or overtreating patients;

(6) use of any advertising statement that is false, misleading, or deceptive;

4. Prior to September 1, 1985, the Texas Food, Drug and Cosmetic Act (Tex. Rev. Civ. Stat. Ann. art. 4476-5) included the following provision:

> Sec. 16 (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and said approval has not been withdrawn under Section 505 of the Federal Act,, or (2) when not subject to the Federal Act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner of Health an application setting f orth (a) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (b) a full list of the articles used as components of such drug; (c) a full

statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Commissioner of Health may require; and (f) specimens of the labeling proposed to be used for such drug.

...

(c) This section shall not apply--

(1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the Commissioner of Health or pursuant to Section 505(i) or 507(d) of the Federal Act...

5. From September 1, 1985, until August 31, 1989, the Texas Food, Drug and Cosmetic Act (Tex. Rev. Civ. Stat. Ann. art. 4476-5) included the following provision:

Sec. 18. (a) A person shall not sell, deliver,, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under section 505 of the Federal Act,, and (2) a copy of the letter of approval or approvability issued by the Federal Food and Drug Administration is on file with the commissioner

if the product is manufactured in this state.

(b) A person shall not use in or on human beings or animals a new drug or new animal drug limited to investigational use unless the person has filed with the Federal Food and Drug Administration a completed and signed "Notice of claimed investigational exemption for a new drug" form in accordance with Section 312.1 of Title 21 of the Code of Federal Regulations (1980) and the exemption has not been terminated. The drug shall be plainly labeled in compliance with Section 505(i) or 507(d) of the Federal Act.

(c) This section shall not apply--

(1) to any drug that is not a new drug as defined in the Federal Act...

6. From September 1, 1989, until August 14, 1992, the Texas Food, Drug and Cosmetic Act contained the following provisions:

Section 431.114:

(a) A person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless:

(1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the Federal Act; and

(2) a copy of the letter of approval or

approvability issued by the Federal Food and Drug Administration is on file with the commissioner if the product is manufactured in this state.

(b) A person shall not use in or on human beings ... a new drug... limited to investigational use unless the person has filed with the Federal Food and Drug Administration a completed and signed "Notice of claimed investigational exemption for a new drug" form in accordance with 21 C.F.R. 312.1 (1980) and the exemption has not been terminated. The drug shall be plainly labeled in compliance with Section 505(i) or 507(d) of the Federal Act.

(c) This section shall not apply:

(1) to any drug that is not a new drug as defined in the Federal Act...

7. The mistake of law defense found at Tex. Penal Code Ann. Section 8.03, prevents a criminal, prosecution when the State misleads a person about the law. That Section states, in part, 11(b) It is an affirmative defense to prosecution that the actor reasonably believed the conduct charged did not constitute a crime and that he acted in reasonable reliance upon: (1) an official statement of the law contained in a written order or grant of permission by an administrative agency charged by law with

responsibility for interpreting the law in question... 11 (emphasis added) . The provisions contained in the Texas Penal Code are not directly applicable to the current administrative law proceedings, as these proceedings are civil in nature. Such provisions contained in the Texas Penal Code, may be considered persuasive in some instances.

8. Based upon Findings of Fact Nos. 5 through 12, and Conclusions of Law Nos. 4, 5, and 7, the mistake of law defense is not applicable in this case to the RESPONDENT'S manufacture and use of antineoplastons prior to May 2, 1988.

9. Based upon Findings of Fact No. 18, the mistake of law defense is not applicable in this case to the RESPONDENT'S manufacture and use of antineoplastons after May 2, 1988.

10. From August 5, 1981, to August 29, 1983, the Texas Medical Practice Act Section 5.09 read as follows:

A person licensed to practice medicine under this Act is authorized to supply the needs of his patients with any drugs or remedies as are necessary to meet the patients' immediate needs; provided,, however, this section does not permit the practitioner to operate a pharmacy without first complying with the Texas Pharmacy Act.

11. From August 29, 1983, to June 14, 1989, the Texas Medical Practice Act Section 5.09 read as follows:

(a) A person licensed to practice medicine under this Act is authorized to supply the needs of his patients with any drugs or remedies as are necessary to meet the patients, immediate needs; provided, however, this section does not permit the physician to operate a retail pharmacy without first complying with the Texas Pharmacy Act.

12. From June 14, 1989, to August 14, 1992, the Texas Medical Practice Act, Section 5.09 read as follows:

> (a) A physician licensed to practice medicine under this Act may supply patients with any drugs, remedies, or clinical supplies as are necessary to meet the patients' immediate needs. This subsection does not permit the physician to operate a retail pharmacy without first complying with the Texas Pharmacy Act.

13. Texas Food, Drug and Cosmetic Act Section 18 and Texas Health and Safety Code Section 431.114 are general provisions of the law. They are directed to all persons. Texas Medical Practice Act Section 5.09 is a special provision of the law directed specifically to physicians licensed by the Texas State Board of Medical Examiners. Read in context, however Section 5.09 of the Texas Medical Practice Act clearly grant physicians only a limited exception to provisions of the (Texas Pharmacy Act.

14. Based upon Conclusions of Law Nos. 4 through 6,,

and 10 through 13, the provisions of Texas Medical Practice Act allowing physicians authority to supply "any drugs" necessary to meet the patients " immediate needs does not confer any authority which extends beyond that included within the Texas Food,, Drug and Cosmetic Act. The two statutes are not in conflict.

15. Based upon Findings of Fact Nos. 3, 5 through B,, and 25 through 27, and Conclusions of Law Nos. 31 4, 7t 8, and 11 through 14,, RESPONDENT'S treatment of patients with antineoplastons prior to September 1,, 1985, constituted a violation of Texas Food, Drug and Cosmetic Act (Tex. Rev. Civ. Stat. Ann. art. 4476-5) Section 16,, and,, therefore,, a violation of Texas Medical Practice Act, Section 3.08(4).

16. Based on Findings of Fact Nos. 3, 5 through 8, and 25 through 27, and Conclusions of Law 3,5,7,8, and 10 through 14, RESPONDENT'S treatment of patients with antineoplastons from September 1, 1985, through August 31, 1989, constituted a violation of Texas Food, Drug and Cosmetic Act (Tex. Rev. Civ. Stat. Ann. art. 4476-5) Section 18, and,, therefore a violation of Texas Medical Practice Act, Section 3.08 (4).

17. Based on Findings of Fact Nos. 27 and 29, and Conclusions of Law Nos. 3,, 6 through 8, and 10 through 14,, RESPONDENT'S treatment of patients with antineoplastons

from September 1, 1989 through August 14, 1992, constituted a violation of the Texas Food, Drug and Cosmetic Act as contained in Section 431.114 of the Health and Safety Code.

18. Based on Findings of Fact Nos. 27 and 29, and Conclusions of Law Nos. 3, 16, and 17, RESPONDENT'S treatment of patients with antineoplastons subsequent to May 2, 1988, constituted a violation of Texas Medical Practice Act, Section 3.08 (4).

19. The Texas Food, Drug and Cosmetic Act bans false advertising in Health and Safety Code Section 431.021, which states:

> "The following acts and the causing of the following acts within this state are unlawful and prohibited... (f) the dissemination of any false advertisements"

20. "Advertising" is defined in Health and Safety Code Section 431.002, as "'Advertising' means all representations disseminated in any manner or by means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics."

21. The Texas Food, Drug and Cosmetic Act states at Health and Safety Code Section 431.183:

> (a) An advertisement of a drug or device is false if the advertisement represents that the drug or device affects:

(2) neoplasms;

(b) Subsection (a) does not apply to an advertisement of a drug or device if the advertisement does not violate section 431.182 and is disseminated:

(1) to the public for self-medication and is consistent with the labeling claims permitted by the Federal Food and Drug Administration;

(2) only to members of the medical, dental, and veterinary professions and appears only in the scientific periodicals of those professions; or

(3) only for the purpose of public health education by a person not commercially interested, directly or indirectly, in the sale of the drug or device.

22. Advertising which is defined as false under the provisions of Section 431.183 of the Health and Safety Code, as referenced in Conclusion of Law No. 21, are false under Texas Medical Practice Act, Section 3.08 (6).

23. Based upon Findings of Fact Nos. 30, 31 and 33 and Conclusions of Law Nos. 19 through 21, the RESPONDENT, between September 1, 1989, and August 14, 1992, has violated the Texas Food, Drug and Cosmetic Act Section 431.183 which constitutes a violation of the Texas Medical Practice Act Section 3.08(4)(A).

24. Based upon Finding of Fact No. 28, the RESPONDENT did not violate the Texas Food, Drug and

Cosmetic Act Section 431.183 between September 1, 1985, and September 1, 1989, as alleged, inasmuch as the specified section of the Health and Safety code was not in effect during that period of time.

25. Based upon Findings of Fact Nos. 30, 31 and 33, and Conclusions of Law Nos. 3, 21, and 22, the RESPONDENT'S brochure is in violation of the Texas Medical Practice Act, Section 3.08(6).

26. Federal regulations, at 21 C.F.R. Section 312.7(d) prohibit charging a fee for an investigational drug in a clinical trial under an IND.

27. Based upon Findings of Fact Nos. 32, 33 and 35 the RESPONDENT has not charged a fee for antineoplastons in violation of the Federal regulations found at 21 C.F.R. Section 312.7(d).

28. Based upon Findings of Fact Nos. 34 through 36, and Conclusion of Law No. 3, there is insufficient evidence to find that RESPONDENT has persistently and flagrantly overcharged any patient.

29. Based upon Conclusions of Law No. 17, Count IA against the RESPONDENT was proven by a preponderance of the evidence.

30. Based upon Conclusions of Law No. 16, Count IB against the RESPONDENT was proven by a preponderance of

the evidence.

31. Based upon Conclusions of Law No. 15, Count IC against the RESPONDENT was proven by a preponderance of the evidence.

32. Based upon Finding of Fact No. 25, and Conclusions of Law Nos. 15 and 16, Count ID against the RESPONDENT was proven by a preponderance of the evidence.

33. Based upon Conclusions of Law Nos. 15 through 17, Count II against the RESPONDENT was proven by a preponderance of the evidence.

34. Based upon Conclusion of Law Nos. 23 and 25, Count III against the RESPONDENT was partially proven by ~~5~~ preponderance of the evidence.

35. Based upon Conclusions of Law No. 24, Count III against the RESPONDENT was not proven by a preponderance of the evidence as the Count relates to the time prior to the enactment of Health and Safety Code section 431.183 and as it relates to the Texas Medical Practice Act Section 3.08(6).

36. Based upon Conclusions of Law Nos. 26 and 27, Count IV against the RESPONDENT was not proven by a preponderance of the evidence.

37. Pursuant to Section Nos. 4.01(a) and 4.12 of the Texas Medical Practice Act, and based on Conclusions of Law Nos. 15 through 18, 23 through 25, and 29 through 34, both

jointly and severally, the Board is authorized to cancel or revoke Respondent's license to practice medicine; administer a public reprimand; suspend, limit or restrict Respondent's license to practice medicine, including limiting his practice to or exclusion of one or more specified activities of medicine or stipulating periodic Board review; to require Respondent to submit to care, counseling, or treatment of physicians designated by the Board as a condition for the continuance of his license -to practice medicine; require RESPONDENT to participate in a program of education or counseling as prescribed by the Board; require Respondent to his practice under the direction of a physician designated by the Board for a specified period of time; and require RESPONDENT to perform public service considered appropriate by the Board. Provided, if the Board determines that, through the practice of medicine, RESPONDENT poses a continuing threat to the public welfare, it is required to revoke or suspend RESPONDENT'S license. Pursuant to Section No. 4.11 of the Texas Medical Practice Act,, the Board may order that any discipline of RESPONDENT he probated for so long as the probationer conforms to the orders,, conditions,, and rules that the Board may set out as the terms of probation, provided that the Board, at the time of probation, shall set out the period of time that constitutes the probationary period.

38. Section 2001.058, Texas Gov't Code Ann. (Vernon's

Pamphlet 1994) provides:

> A state agency may change a Finding of Fact or Conclusion of Law made by the administrative law judge, or may vacate or modify an order issued by the administrative law judge, only for reasons of policy. The agency shall state in writing the reason and legal basis for a change made under this subsection.

39. Section 1.02(l) of the Texas Medical Practice Act, under Findings and Purposes, provides:

> the practice of medicine is a privilege and not a natural right of individuals and as- a matter of policy it is considered necessary to protect the public interest through the specific formulation of this Act to regulate the granting of that privilege and its subsequent use and control.

40. 22 T.A.C. 187.34(d) provides that:

Changes to Recommendation.

> created by the legislature to protect the public interest as an independent agency of the executive branch of the government of the State of Texas so as to remain as the primary means of licensing, regulating and disciplining physicians and surgeons, consistent with APTRA, Section 13(j) to protect the public interest and ensure that sound medical principles govern the decisions of the board, it shall hereafter be the policy of the board to change a finding of fact or conclusion of law or to vacate or modify the proposed order of an administrative law judge when the proposed order is:
>
> (1) erroneous;
>
> (2) against the weight of the evidence;

(3) based on unsound medical principals;

(4) based on an insufficient review of the evidence;

(5) not sufficient to protect the public interest; or

(6) not sufficient to adequately allow rehabilitation of the physician.

41. The proposal for Decision and Proposed Order of the Administrative Law Judge are each, in part, erroneous, against the weight of the evidence, and not sufficient to protect the public interest.

42. The Board cites each of the following, jointly and severally, as the reason(s) and legal basis for modifying the Proposal for Decision and Proposed Order of the Administrative Law Judge:

a. Conclusions of Law Nos. 1 through 41, jointly and severally;

b. Section 1.02(l) of the Texas Medical Practice Act;

Based on the above Findings of Fact and Conclusions of Law the Board ORDERS that RESPONDENT'S license to practice medicine is suspended; however, the suspension is stayed and RESPONDENT is placed on probation for ten (10) years effective the date of the signing of this Order by the presiding officer of the Board, under the following terms and conditions:

1. RESPONDENT shall comply with all provisions of all statutes and regulations promulgated by the United States of

America or any of its agencies or departments and of all statutes or regulations promulgated by the state of Texas or any of its agencies or departments, relating to the manufacture and/or distribution, by any means, of drugs and/or new drugs.

2. RESPONDENT shall not disseminate, by any means, any advertisement in violation of either the Texas Food, Drug and Cosmetic Act section 431.183 or the Texas Media Practice Act, Section 3.08(6).

3. Respondent shall give a copy of this order to all hospitals and health care entities where he has privileges.

4. Respondent shall cooperate with the Board, its attorneys, investigators, compliance officers, and other employees and agents, to verify that Respondent has complied and is in compliance with this Board Order.

5. Respondent shall advise the Board of any change of address, mailing or office, within (10) days of such occurrence.

6. The time period of this Order shall be extended for any period of time in which Respondent subsequently resides or practices medicine outside the State of Texas, is in official retired status with the Board, or for any period during which Respondent's license is subsequently cancelled for nonpayment of licensure fees. If Respondent leaves Texas to live or practice medicine elsewhere, Respondent shall immediately notify the Board in writing of the dates of Respondent"s departure from

and subsequent return to Texas. Upon Respondent's return to practice in Texas or Respondent's relicensure, Respondent shall be required to comply with the terms of this Order for the period of time remaining on the Order when Respondent left the practice of medicine in Texas, retired, or had his license cancelled for nonpayment of licensure fees.

7. Respondent shall comply with all the provisions of the Medical Practice Act ("the Act"), V.A.C.S., article 4495b, and other statutes regulating the practice of medicine, as is required by law for physicians licensed by the Board, to include such statutes for ensuring informed patient consent to any and all medical treatments rendered.

Any violation of the terms, conditions, and requirements of this Order may constitute evidence of unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public within Section 3.08(4) of the Act, and may result in disciplinary action pursuant to Section 4.01(a) of the Act.

The above-referenced conditions shall continue in full force and effect without opportunity for amendment, except for clear error in drafting, for 12 months following entry of this Order. If, after the passage of the 12 month period, the Respondent wishes to seek amendment or termination of these conditions, then he may petition the Board in writing. The Board may inquire into the request and may, in its sole discretion, grant

or deny the petition.

Petitions for modifying or terminating may be filed only once a year thereafter.

It is further ORDERED that all costs of preparation of the original or a certified copy of the record of the proceedings in this matter which may be required to be transmitted to a reviewing court for appellate purposes be assessed against and paid by Respondent.

SIGNED this 31st day of August 1994.

# EXHIBIT "G"

IN THE UNITED STATES DISTRICT COURT

| | | |
|---|---|---|
| STANISLAW R. BURZYNSKI, M.D. Ph.D, | § | IN THE DISTRICT COURT |
| | § | |
| Plaintiff, | § | |
| vs. | § | OF TRAVIS COUNTY, TEXAS |
| | § | |
| TEXAS STATE BOARD OF MEDICAL EXAMINERS | § | |
| | § | |
| | § | |
| Defendant. | § | 200th JUDICIAL DISTRICT |

## TEMPORARY INJUNCTION ORDER

Plaintiff, STANISLAW R. BURZYNSKI, M.D., Ph.D has filed its Original Petition for Review of agency action and application for TRO and Temporary Injunction against the Defendant, Texas State Board of Medical Examiners. A Temporary Restraining Order has previously been issued, pending the determination by this Court of Plaintiff's Motion for a Temporary Injunction.

The parties having appeared at a hearing and have presented arguments, it appears from the facts and arguments that Dr. Burzynski has demonstrated a likelihood of success on the merits, and that Dr. Burzynski may suffer irreparable injury if the Temporary Injunction is not granted.

IT IS THEREFORE ORDERED that Defendant, Texas State Board of Medical Examiners shall be temporarily enjoined from enforcing the Order issued by it and filed on September 6,

1994 pending the final disposition of this matter by this Court.

The Clerk of the above and entitled Court shall forth with issue a Temporary Injunction in conformity with the law and terms of this Order.

This Order shall be effective without the execution and filing of a bond as the Defendant, Texas State Board of Medical Examiners has no financial or pecuniary interest in this matter.

This case is set for hearing on the merits on the 3rd day of February, 1995, at 2:00 o'clock, p.m.

Plaintiff's Initial Brief is due on December 23, 1995.

Defendant's Responsive Brief is due on January 13, 1995.

Plaintiff's Reply Brief is due on January 27, 1995.

Signed this 10th day of November, 1994.

DISTRICT JUDGE PAUL DAVIS

# EXHIBIT "H"

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

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| TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST FUND | § | CIVIL ACTION NO. H-91-347 |
| VS. | § | JURY TRIAL REQUESTED |
| STANISLAW R. BURZYNSKI | § | |

**PLAINTIFFS' SECOND AMENDED COMPLAINT**

## THE PARTIES

1. Plaintiffs are the Trustees for the Northwest laundry and Dry cleaners Health & Welfare Trust Fund (The Trust). the Trust is self-insured and provides health insurance benefits for employees and their dependents who are covered by the terms and conditions of written collective bargaining agreements between Textile Processors Local No. 107 and various employers in the laundry and dry cleaning industries in Oregon, Southwest Washington and Idaho. The Trust is any employee welfare benefit plan pursuant to the provisions of 29 USC §1002(1) of the Employee Retirement Income Security Act of 1974 (ERISA). The Trustees are fiduciaries under 29 USC §1002(2(A) of ERISA.

2. At all times material to this lawsuit, the Trust's

principal place of business and the place where the Trust is administered has been in Portland, Oregon. The Trustees for the Trust reside in the state of Oregon.

3. Defendant Stanislaw R. Burzynski (Defendant Burzynski) is and at all times relevant herein has been duly licensed by the state of Texas to practice medicine and has been residing and practicing medicine in the state of Texas.

SUBJECT MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS AND VENUE

4. The court has federal question jurisdiction over Plaintiffs' Second Claim for Relief, which alleges RICO violations, pursuant to 28 USC §1331.

5. The Court has jurisdiction over Plaintiffs' Third Claim for Relief, which alleges violations of ERISA, pursuant to the provisions of 28 USC §1331 and 29 USC §1132(a)(3) of ERISA.

6. The Court also has diversity jurisdiction over Plaintiffs' First, Second and Third Claims for Relief pursuant to 28 USC §1332. This action is of a civil nature involving, exclusive of interest and costs, a sum in excess of $50,000.00. Plaintiffs, at all times material herein, have been domiciled in and are residents of the state of Oregon. Upon information and belief, Defendant Burzynski is a resident of the state of Texas but, in no event, has Defendant Burzynski been a resident of the state of

Oregon.

7. The Court should assume pendent jurisdiction over Plaintiffs' First Claim for Relief which alleges fraud for the following reasons:

(a) the Court has jurisdiction over Plaintiffs' Second and Third Claims for Relief, which allege RICO violations and ERISA violations, pursuant to 28 USC §1331 and 29 USC §1132(a)(3);

(b) the action for fraud is based on the same operative facts which are alleged in Plaintiffs' RICO and ERISA claims; and

(c) judicial economy, convenience and fairness to the parties will result if the Court assumes and exercises jurisdiction over Plaintiffs' First Claim for Relief.

8. Venue is proper in this Court for Plaintiffs' First, Second and Third Claims for relief pursuant to the provisions of 28 USC §1391(b) since this is an action not founded solely on diversity of citizenship and the claim against Defendant arose in Portland, Oregon.

9. Venue is also proper over Plaintiffs' Third Claim for relief, which alleges ERISA violations pursuant to the provisions of 29 USC §1132(e)(2) because the Trust is administered in Portland, Oregon, and the violation of ERISA took place in Portland, Oregon.

## FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

10. At all times material to this proceeding, Huey Roberts was a resident of Boring, Oregon, and a participant in the Trust.

11. At all times material to this proceeding, t he Trust has employed Kipp and Company to serve as its administrator. Kipp & Company's sole place of business is in the state of Oregon. As administrator for the Trust, Kipp & Company's duties include the payment of certain health insurance claims incurred by participants of the Trust. The claims are paid out of Trust assets.

12. From 1978 to the present, Defendant Burzynski has authored articles, submitted to interviews, made television and radio appearances and produced and disseminated brochures concerning antineoplastons (ANPA) for the treatment of cancer. The publications, public utterances and dissemination of brochures and other material were intended to, and did in fact, reach residents of the state of Oregon.

13. Upon information and belief, Defendant Burzynski and his agents and employees have spoken with residents of the state of Oregon by telephone concerning the antineoplastons therapy and its effectiveness in the treatment of cancer.

14. In 1986, Mr. Roberts was diagnosed with having esophageal cancer metastatic to his lung. Between 1986, when

Mr. Roberts was diagnosed with having cancer, and April 1988, Mr. Roberts received materials, brochures and information prepared by Defendant Burzynski and his employees and agents, through the mail and by telephone, at his home in Boring, Oregon, concerning the antineoplastons therapy for the treatment of cancer.

15. In April 1988, after receiving brochures and other information prepared by Defendant Burzynski and his employees and agents concerning the use of antineoplastons therapy for the treatment of cancer, Mr. Roberts traveled from Boring, Oregon, to Houston, Texas, where Defendant Burzynski and his employees and agents began to administer antineoplastons therapy continued through on or about March 15, 1989.

16. Defendant Burzynski began to treat Mr. Roberts with antineoplastons therapy only after determining Mr. Roberts had medical insurance through the Trust.

17. Defendant Burzynski undertook to treat other cancer patients with antineoplastons therapy, who were situated similarly to Mr. Roberts, knowing they had medical insurance benefits administered and/or paid by insurers and/or other third-party payors.

18. At times between April 28, 1988, and on or about March 15, 1989, the antineoplastons therapy was administered to Mr. Roberts by Defendant Burzynski and his employees and

agents in Houston, Texas. At other times between April 28, 1988, and or about March 15, 1989, Mr. Roberts administered the antineoplastons therapy to himself in Boring, Oregon.

19. During the time Defendant Burzynski was treating Mr. Roberts, Defendant Burzynski and his agents and employees filled out and sent through the United States mail numerous health insurance claim forms to the Trust in care of Kipp and Company in Portland, Oregon, for the antineoplastons therapy and related treatment administered to Mr. Roberts. Agents and employees of Defendant Burzynski also had telephone conversations with employees of Kipp & Company in Portland, Oregon, concerning the services Defendant Burzynski performed on behalf of Mr. Roberts.

20. The medical bills Defendant Burzynski and his agents and employees submitted to the Trust in care of Kipp & Company on behalf of Mr. Roberts were intentionally misleading in that the bills were made to appear that Mr. Roberts was receiving legitimate chemotherapy when, in fact, antineoplastons therapy has no proven medical value in the treatment of cancer. In addition, the medical bills were made to appear that the antineoplastons therapy was being personally administered to Mr. Roberts by Defendant Burzynski and his agents and employees in Houston, Texas, when, in fact, for substantial periods of time between April 27, 1988, and or about March 15, 1989, the

antineoplastons therapy was self-administered by Mr. Roberts in his home in Boring, Oregon.

21. As a direct result of bills Defendant Burzynski sent to the Trust in care of Kipp & Company, the Trust, from on or about October 11, 1988, through May 31, 1989, sent 13 checks totalling $96,963.56 to Defendant Burzynski. The checks were for payment of the antineoplastons therapy and related services Defendant Burzynski and his agents and employees performed on behalf of Mr. Roberts. The checks were sent from Portland, Oregon, and drawn on the First Interest Bank of Oregon at its home office in Portland, Oregon. Defendant Burzynski cashed the 13 checks which the Trust sent to him.

## PERSONAL JURISDICTION OVER DEFENDANT BURZYNSKI

22. The Court has personal jurisdiction over Defendant Burzynski pursuant to the provisions of Rule 4A.(4), Rule 4C., Rules 4D.(1) and (2), Rule 4E.(5) and/or Rule 4L. of the Oregon Rules of Civil Procedure.

## FIRST CLAIM FOR RELIEF - FRAUD

23. The Texas Department of Health determined that the use of antineoplastons therapy for the treatment of cancer constitutes a violation of Section 18 of the Texas Food, Drug and Cosmetic Act Article 4476-5, Texas Revised Civil Statutes and on May 2, 1988, wrote a letter to Defendant Burzynski advising him

of its findings. A copy of the letter from the Texas Department of Health to Defendant Burzynski is attached to Plaintiffs' Second Amended Complaint as Exhibit A and incorporated herein. It has been a violation of Texas law for Defendant Burzynski and his agents and employees to treat patients with antineoplastons therapy within the state of Texas at least from May 2, 1988, to date.

24. Defendant Burzynski and his agents and employees knew it was unlawful to treat cancer patients with antineoplastons therapy in Texas at least from May 2, 1988, to date. In spite of the findings of the Texas Department of Health, Defendant Burzynski treated Mr. Roberts with antineoplastons therapy in Texas from on or about April 27, 1988, through on or about March 25, 1988.

25. Defendant Burzynski and his agents and employees intentionally concealed and intentionally failed to disclose to the Trust and its administrator, Kipp & Company, that the use of antineoplastons therapy that was administered to Mr. Roberts was unlawful in the state of Texas.]

26. The fact that antineoplastons therapy was unlawful in the state of Texas was material to the Trust in that the Trust would not have paid Defendant Burzynski's bills totalling $96,963.56 for antineoplastons therapy and related services on behalf of Mr. Roberts has it known the antineoplastons therapy

was unlawful in Texas.

27. Defendant Burzynski and his agents and employees knew the fact that the antineoplastons therapy administered was unlawful in the state of Texas would be a material consideration and of material importance in the Trust's consideration of whether his bills for antineoplastons therapy on behalf of Mr. Roberts would be paid because neither Mr. Roberts nor the Trust had an obligation to pay a medical bill for treatment which was unlawful. Defendant Burzynski and his agents and employees also intentionally failed to disclose to the Trust that large portions of the antineoplastons therapy were being self-administered by Mr. Roberts in Boring, Oregon. The reason for this concealment was that Defendant Burzynski knew the location of the treatment and the fact that substantial portions of it were self-administered was material to the Trust and would have resulted in the denial of the payment of his bills.

28. The Trust and its administrator, Kipp & Company, first became aware it was unlawful for Defendant Burzynski to sue antineoplastons therapy in the treatment of cancer in the state of Texas on or about February 23, 1990.

29. The Trust relied on and believed the medical bills Defendant Burzynski submitted on behalf of Mr. Roberts were for lawful treatment which was medically necessary and was being administered to Mr. Roberts directly by Defendant Burzynski and

his employees and agents.

30. Because of Defendant Burzynski's intentional concealment and intent to deceived the Trust and Kipp & Company that the bills for antineoplastons therapy were for a treatment which was unlawful in the state of Texas and the antineoplastions therapy was not personally administered to Mr. Roberts by Defendant Burzynski for substantial periods of time, the Trust has been damaged. The Trust has been damaged in the sum of $96,963.56 which represents the amount of money the Trust paid to Defendant Burzynski for the medical bills he submitted on behalf of Mr. Roberts for the unlawful antineoplastons therapy and related treatment.

31. Defendant Burzynski's actions were willful and wanton and justify an award of punitive damages in the sum of $350,000.00

SECOND CLAIM FOR RELIEF - RICO VIOLATIONS

32. Plaintiffs reallege and incorporate by reference paragraphs 1 through 31 of their Second Amended Complaint as though fully set forth herein.

33. Defendant Burzynski is a person within the meaning of 18 USC §1961(3).

34. The Trust is a person pursuant to 18 USC §§1961(3) and 1965(c). The Trust as been injured in its business or property by reason of Defendant Burzynski's violation of 18

USC §1962.

35. The Burzynski Research Institute, Inc. is, and at all material times alleged herein has been, a corporation organized under the laws of the state of Texas. The Burzynski Research Institute, Inc. is a medical clinic operated by Defendant Burzynski. The Burzynski Research Institute, Inc. consists of a facility for the production of antineoplastons and a clinic in which Defendant Burzynski and his agents and employees administer antineoplastons therapy to cancer patients.

36. Defendant Burzynski, his agents and employees, the Burzynski Research Institute, Inc. and other individuals associated with Defendant Burzynski and the Burzynski Research Institute, Inc. are associated for the purpose of defrauding the Trust as well as insurance carriers and other payors of health insurance benefits by submitting bills for antineoplastons therapy which is unlawful in the state of Texas and which is not a recognized medication for the treatment of cancer. Defendant Burzynski, the Burzynski Research Institute, Inc. and the individuals associated with them constitute an enterprise within the meaning of 18 USC §1961(4).

37. Defendant Burzynski has repeatedly and continuously defrauded the Trust by a pattern of racketeering activity which includes:

a. embezzlement from the Trust in violation

of 18 USC §664 in that 13 separate checks were obtained by Defendant Burzynski from the Trust based on bills for antineoplastons therapy. The bills were false and misleading in that they failed to disclose antineoplastons therapy was unlawful in the state of Texas, the bills were intended to cause the Trust to believe antineoplastons therapy was a conventional and recognized method for the treatment of cancer when, in fact, antineoplastons therapy has no proven value in the treatment of cancer and the bills were intended to cause the Trust to believe antineoplastons therapy was being administered to Mr. Roberts by Defendant Burzynski when, in fact, substantial portions of the antineoplastons therapy were self-administered by Mr. Roberts and

b. mail fraud in violation of 18 USC §1341 in that Defendant Burzynski and his agents and employees sent numerous medical claim forms through the United States mail to the Trust in care of its administrator, Kipp & Company. The claim forms were false and misleading in that they failed to disclose antineoplastons therapy was unlawful in the state of Texas, the bills were intended to cause the Trust to believe antineoplastons therapy was a conventional and recognized method for the treatment of cancer when, in fact, antineoplastons therapy has no proven value in the treatment of cancer and the bills were intended to cause the Trust to believe antineoplastons

therapy was being administered to Mr. Roberts by Defendant Burzynski when, in fact, substantial portions of the antineoplastons therapy were self-administered by Mr. Roberts.

38. Because of the fraudulent acts of Defendant Burzynski and his agents and employees as set forth above, the Trust sent Defendant Burzynski, through the United States mail, 13 checks totalling $96,963.65 for the antineoplastons therapy and related treatment administered to Mr. Roberts.

39. The Trust believes other insurance carriers and payors of health insurance claims have received similar fraudulent claim forms from Defendant Burzynski for antineoplastons therapy through the United States mail.

40. The Trust believes Defendant Burzynski continues to treat cancer patients with antineoplastons therapy which is unlawful in Texas and continues to submit fraudulent bills to health insurance carriers and other payors of health insurance claims for antineoplastons therapy.

41. The false and fraudulent representations, omissions and schemes to defraud the Trust, health insurance carriers, other payors of health insurance claims and cancer patients by Defendant Burzynski and his agents and employees constitutes a pattern of racketeering activity as defined by 18 USC §1961(5).

42. The acts and omissions as alleged above constitute

two or more acts of racketeering activity, all of which occurred after the effective date of the RICO statute and more than on of which occurred within ten years after the commission of a prior act of racketeering activity. Each of the racketeering acts alleged herein bore a direct relationship to the overall cancer treatment enterprise described above.

43. As a direct and proximate result of the pattern of racketeering activity engaged in by Defendant Burzynski and his agents and employees, the Trust has suffered damages to its business and property in that it made payments totalling $96,963.56 from October 1, 1988, through May 31, 1989, to Defendant Burzynski for antineoplastons therapy and related treatment rendered on behalf of Mr. Roberts. Pursuant to the provisions of 18 USC §1963(c), the Trust is entitled to recover from Defendant Burzynski three-fold that amount as its damages, together with interest thereon and an award of reasonable attorney's fees.

THIRD CLAIM FOR RELIEF - ERISA VIOLATIONS

44. Plaintiffs reallege and incorporate by reference paragraph 1 through 31 of their Second Amended Complaint as though fully set forth herein.

45. Between October 11, 1988, and May 31, 1989, the Trust erroneously paid to Defendant Burzynski $96,963.56 for administering antineoplastons therapy to Mr. Roberts.

46. The payments which the trust made to Defendant Burzynski were ineligible expenses not entitled to payment because the Trust had not legal obligation to pay for the expense incurred for which Mr. Roberts was not legally liable. Mr. Roberts was not legally liable to pay Defendant Burzynski's medical bills for antineoplastons therapy since the bills were for a treatment which was illegal in the state of Texas. Whatever contractual obligation Mr. Roberts may have had to pay Defendant Burzynski for the antineoplastons therapy was illegal and void.

47. Pursuant to the provisions of 29 UCS §1132(a)(3) of ERISA, Defendant Burzynski should be required to make restitution to the Trust in the sum of $96,963.56.

48. Pursuant to the provisions of 29 USC §1132(g)(1) the Trust should be awarded a reasonable attorney's fee for the time and expense associated with pursuing this claim against Defendant Burzynski.

WHEREFORE, Plaintiffs pray for a decree and judgment against Defendant Burzynski as follows:

1. Under Plaintiffs' First Claim for Relief, for judgment requiring Defendant Burzynski to pay $96,963.56 in general damages, $350,000.00 in punitive damages, and a reasonable attorney's fee;

2. Under Plaintiffs' Second Claim for Relief, for

judgment requiring Defendant Burzynski to pay $290,890.68 in damages, interest thereon and a reasonable attorneys' fee;

3. Under Plaintiffs' Third Claim for Relief, for judgment requiring Defendant Burzynski to pay $96,963.56 and a reasonable attorneys' fee.

4. For pre-judgment and post judgment interest at the highest lawful rates and Plaintiffs' costs and disbursements incurred herein; and

5. For such further relief as the Court deems just and equitable.

Respectfully submitted,

HARDIN, BEERS, HAGSTETTE, & DAVIDSON

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ATTORNEYS FOR PLAINTIFFS

## CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was forwarded via certified mail, return receipt requested or hand delivery on this the _____ day of _____, 1991, to:

Richard A. Jaffe
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_____
Brad Beers